



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

345 04 13 17 000  
AUG 31 2004

Mr. Charles L. Schel  
President  
Dietary Supplement Systems Global, Inc.  
810 Millstream Lane  
Ormond Beach, Florida 32174

Dear Mr. Schel:

This is in response to your letter of July 1, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Dietary Supplement Systems Global, Inc. is making the following claim, among others, for the product INTESTAID:

“[H]armful bacteria (E-Coli) are reduced.”

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely enteric disease caused by pathogenic *Escherichia coli*. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

975-0163

LET 776

Page 2 - Mr. Charles L. Schel

Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'S. Walker', with a long horizontal flourish extending to the right.

Susan J. Walker, M.D.  
Director  
Division of Dietary Supplement Programs  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Florida District Office, Office of Compliance, HFR-SE240

FDA, Los Angeles District Office, Office of Compliance, HFR-PA-240

Copy:

Dietary Supplement Systems Global, Inc.

ATTN: Charles L. Schel

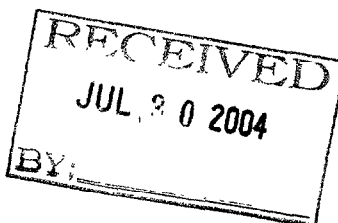
818 Cheney Court

Lodi, California 95242



**DIETARY SUPPLEMENT SYSTEMS GLOBAL, INC.**

East: 810 Millstream Lane, Ormond Beach, FL 32174 Tel/Fax: -1-386-586-0155  
West: 818 Cheney Court, Lodi, CA 95242 Tel: 1-209-333-9680 Fax: 1-209-366-1859



July 1, 2004

The Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, DC 20204

Dear Sir or Madam:

Notice is hereby given that Dietary Supplement Systems Global, Inc., 810 Millstream Lane, Ormond Beach, FL, 32174 and 818 Cheney Court, Lodi, CA 95242, will market a dietary supplement under the *INTESTAID* brand name bearing the following statements on the label and/or in the labeling and product information pamphlet:

**Intestinal Balance Supplement**

"Helps maintain normal bowel function."

"Helps maintain normal colon function and intestinal health."

"These active ingredients in Intestaid IBS help support the body's natural cell regeneration process and influence changes in intestinal microflora which helps maintain efficient colonic function and intestinal health; beneficial (bifido) bacteria increase while harmful bacteria (E-Coli) are reduced}."

The product contains vitamins C and E along with folic acid, vitamin B12, biotin, pantothenic acid and concentrated extracts of *Saccharomyces cerevisiae*.

The undersigned certifies that the information contained in this notice is complete and accurate and that DSS Global has substantiation that the statements are truthful and not misleading. Pursuant to 21 CFR §101.93(a)(1), two copies of this notification are enclosed.

Sincerely,

Charles L. Schel  
President, DSS Global, Inc.

89297



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Charles L. Schel  
President, DSS Global, Inc.